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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,649	08/01/2000	DANIEL LADANT	03495.0190	8848

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EXAMINER
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ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/16/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/555,649

Examiner

Robert A Zeman

Applicant(s)

LADANT ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2002.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 23, 24 and 39-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-22 and 25-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 11.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

#### ***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12-28-2001 has been approved.

The formal drawings incorporating the approved changes filed on 12-28-2001 have been received. Said drawings have been submitted to the draftsman for approval.

#### ***Election/Restriction***

Applicant's election of Group II in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-45 are pending. Claims 1-9, 23-24 and 39-45 have been withdrawn from consideration. Claims 10-22 and 25-38 are currently under examination.

#### ***Claim Objections***

Claims 10 and 25 objected to because of the following informalities: said claims are dependent on a non-elected claim. Said claims are dependent on claim 1. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-22 and 25-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 16 and 25-38 are rendered vague and indefinite by the use of the term "capable of". Having the capacity do something is not analogous to that "something" actually being done. Therefore, it is impossible to determine the metes and bounds of the claimed invention.

Claim 10 is rendered vague and indefinite by the use of the term "generating a signal amplification". It is unclear what is meant by said term. Is Applicant referring to the generation of a signal or the amplification of a signal?

Claim 12 is rendered vague and indefinite by the use of the term "leads to". It is unclear what is meant by said term. It is suggested that the term "results in" be used in lieu of said term.

Claims 14 and 27 are rendered vague and indefinite by the use of the term "whose activity is restored". It is unclear whether Applicant is referring to the activity of the enzyme or the modulator.

Claims 15 and 32 are vague and indefinite since the term "ligand", which is being characterized by the Markush group, is also listed as a member of said Markush group.

Claims 19 and 35 are rendered vague and indefinite by the use of the phrase "signaling molecule corresponds to the synthesis of cGMP". It is unclear how a "molecule" can be defined as a process.

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Claims 18 and 34 are rendered vague and indefinite by the use of the phrase "signaling molecule corresponds to the synthesis of cAMP". It is unclear how a "molecule" can be defined as a process.

Claims 20 and 36 recite improper Markush language. The penultimate member of the recited group should be followed by the conjunction "and".

Regarding claims 20 and 36, the phrases "such as" and "of the type of" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 20 and 36 are rendered vague and indefinite by the use of the term "the reporter gene expression is selected from the group consisting of ...". It is unclear how a process/function can be defined as a gene.

Claims 21 and 37 are rendered vague and indefinite by the use of the term "mutant molecule". It is unclear what is meant by said term. For example, what is a mutant peptide and how does it differ from a "wild-type peptide"?

Claims 22 and 38 are rendered vague and indefinite by the use of the phrase "an *E. coli* strain, or in any bacterial deficient in endogenous adenylate cyclase or any other eukaryotic cell". The aforementioned are listed as components in a kit. It is unclear what is meant by "in any bacterial strain". Is Applicant claiming all bacterial strains that are deficient in endogenous adenylate cyclase or an *E. coli* strain in another bacterial strain? It is unclear what is meant by "any other eukaryotic cells" since the only organisms previously listed are prokaryotes and the claims recite a "bacterial" multihybrid system. Additionally, the aforementioned claims recite

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improper Markush language with regard to the various types of medium. Specifically, members of the Markush contain the "or" variable. Consequently it is impossible to determine exactly what limitations each member of the Markush group possess.

Claim 25 is rendered vague and indefinite by the use of the term "generating an amplification". It is unclear what is meant by said term. Is Applicant referring to the amplification of a signal? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 33 is rendered vague and indefinite by the use of term "having stimulating or inhibitory affinity". It is unclear what is meant by said term. As such it is impossible to determine the metes and bounds of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-17, 20-22, 25-33 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Fields et al. (U.S. Patent 5,468,614 – IDS-11).

The instant claims are drawn to methods of selecting a molecule of interest that can bind to a target ligand utilizing signal amplification system comprising a bacterial multi-hybrid system utilizing enzyme fragments and/or enzyme modulators to detect protein-protein interactions. The instant claims are also drawn to methods wherein said selection is done in

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*Escherichia coli* or any bacterial strain or eukaryotic cell deficient in endogenous adenylate cyclase or any other eukaryotic cell.

Fields et al. disclose a yeast based system for detecting protein-protein interactions whereby the interaction between a first test protein and a second test protein is detected *in vivo* using reconstitution of the activity of a transcriptional activation. The disclosed system makes use of chimeric genes to express the hybrid proteins. Fields et al. further disclose that 2 types of hybrid proteins are used in their system. The first is the test protein fused to the DNA binding domain of a transcriptional activator. The second contains a transcriptional activator fused with the second test protein. If the two test proteins can interact, the two domains of the transcriptional activator are brought into close proximity allowing it to cause transcription of a marker gene that contains a binding site for the DNA binding domain. Said test proteins can be any proteins or protein fragments that are capable of interacting (see column 4, lines 37-40 and lines 50-54). Fields et al disclose generally applicable methods for detecting any detectable function requiring separable domains of an amino acid sequence which can be reconstituted (see column 7, lines 50-55). Furthermore, Fields et al. disclose that said amino acid sequence might be derived from a bacterial protein, a viral protein, an oncogene-encoded protein, a growth factor or an **enzyme**. Consequently, Fields et al. anticipates all the limitations of the claimed invention.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



ROBERT A. ZEMAN  
PRIMARY EXAMINER

Robert A. Zeman  
July 12, 2002